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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,826	01/05/2004	Cecile Casterman	04958.0008-08000	4193

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,826	CASTERMAN ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 6/28/04 is acknowledged and has been entered.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 18-36 and 51-59, drawn to an immunoglobulin or fragment thereof comprising a VH polypeptide, and composition thereof, classified in Class 530, subclass 387.1 and Class 424, subclass 130.1, respectively.

II. Claims 37 and 38, drawn to a method for detecting the presence of a bacterium, virus or parasite in a biological sample comprising contacting the biological sample with an immunoglobulin specific for an antigen of the bacterium, virus or parasite, and detecting binding of the immunoglobulin, classified in Class 435, subclass 5.

III. Claim 39, drawn to a method for detecting the presence of a tumor in a biological sample comprising contacting the biological sample with an immunoglobulin that specifically binds a protein present ***on*** the said tumor, and detecting binding of the immunoglobulin, classified in Class 435, subclass 7.23.

IV. Claim 40, drawn to a method for detecting the presence of a myeloma [protein] in a biological sample comprising contacting the biological sample with an immunoglobulin specific for a myeloma immunoglobulin epitope, and detecting binding of the immunoglobulin, classified in Class 435, subclass 7.1. (The Examiner notes that although a myeloma is a tumor, the immunoglobulin made by the myeloma tumor is ***secreted***, and ***not present on*** the tumor cell.)

V. Claims 44 and 45, drawn to a method for detecting the presence of a bacterium, virus, or parasite in a subject comprising administering an immunoglobulin specific for a bacterial, viral or parasite antigen, and detecting binding of the immunoglobulin, classified in Class 424, subclass 130.1.

VI. Claim 46, drawn to a method for detecting the presence of a tumor in a subject comprising administering an immunoglobulin that specifically binds a protein present ***on*** the said tumor, and detecting binding of the immunoglobulin, classified in Class 424, subclass 134.1.

VII. Claim 47, drawn to a method for detecting the presence of a myeloma in a subject comprising administering an immunoglobulin specific for a myeloma immunoglobulin epitope, and detecting binding of the immunoglobulin, classified in Class 424, subclass 131.1. (The Examiner notes that although a myeloma is a tumor, the immunoglobulin made by the myeloma tumor is ***secreted***, and ***not present on*** the tumor cell.)

VIII. Claim 60, drawn to a method of treating cancer in a mammal comprising administering to said mammal a composition comprising an immunoglobulin or fragment thereof that specifically binds a tumor-specific protein, classified in Class 424, subclass 138.1.

IX. Claim 61, drawn to a method of inducing protection against a pathological agent in a mammal comprising administering to said mammal a composition comprising an immunoglobulin or fragment thereof that specifically binds an antigen of said pathological agent, classified in Class 424, subclass 147.1.

X. Claim 62, drawn to a method of regulating the expression or the activity of a protein in a mammal comprising administering a composition comprising an immunoglobulin or fragment thereof that binds to said protein, classified in Class 424, subclass 156.1.

Note Absent evidence to the contrary, each of the methods comprising administering the recited composition comprising an immunoglobulin or fragment thereof is distinct since each ligands(s) to which each of said immunoglobulin or fragment thereof is specific for is not obvious over the other set of ligand(s), and the method regulates the expression or activity of a distinct protein with a distinct biological function and mode of activity that is not obvious over the other set of proteins. Therefore instant claim 62 encompasses hundreds of GROUPS, not species.

For example, a GROUP would be a method of decreasing IL-2 activity comprising administering to a mammal an immunoglobulin or fragment thereof comprising a VH polypeptide, wherein the immunoglobulin or fragment thereof specifically binds IL-2 and decreases IL-2 activity.

XI. Claim 63, drawn to a method of **increasing** the metabolism of a cell comprising administering an immunoglobulin or fragment thereof, classified in Class 424, subclass 152.1.

XII. Claim 63, drawn to a method of **decreasing** the metabolism of a cell comprising administering an immunoglobulin or fragment thereof, classified in Class 424, subclass 152.1.

Claims 41-43 link inventions II, III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 41-43.

Claims 48-50 link inventions V, VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 48-50.

Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Inventions (I) [product] and Inventions (II-XII) [methods] are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or in any of the ten distinct processes of Inventions II-XII.

4. Inventions II-XII are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of: detecting the presence of a bacterium, virus or parasite in a biological sample (II), detecting the presence of a tumor in a biological sample (III), detecting the presence of myeloma in a biological sample (IV), detecting the presence of a bacterium, virus or parasite in a subject by administering an immunoglobulin and detecting binding (V), detecting the presence of a tumor in a subject by administering an immunoglobulin and detecting binding (VI), detecting the presence of a myeloma in a subject by administering an immunoglobulin and detecting binding (VII), treating cancer in a mammal comprising administering an immunoglobulin that binds a tumor-specific protein (VIII), inducing protection against a pathological agent in a mammal comprising administering an immunoglobulin that binds to an antigen of the pathological agent (IX), regulating the expression or activity of a protein in a mammal comprising administering a composition comprising an immunoglobulin that binds to said protein (X), modifying, *i.e.*, increasing or decreasing, the metabolism of a cell comprising administering an immunoglobulin (XI and XII).

The antibodies of II, V, IX are specific for an antigen of a pathological agent such as a parasite, virus or bacterium, whereas the antibodies of III, VI and VIII are specific for a tumor antigen, whereas the antibodies of IV, VII are specific for an immunoglobulin idiotype. The methods of II, III and IV are *in vitro* detection methods using biological samples, whereas the methods of V, VI and VII are *in vivo* detection methods wherein immunoglobulin is administered *in vivo*, whereas the methods of VIII, IX, X, XII and XI are *in vivo* administration methods, *i.e.,* the method of VIII is to treat cancer in a mammal, the method of IX is to immunize a mammal against a pathological agent, the methods of X are to regulate the activity or expression of protein in a mammal, the method of XI is to increase the metabolism of a cell, and the method of XII is to decrease the metabolism of a cell.

Therefore they are patentably distinct.

5. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XII is not required for any other group from Groups I-XII and Groups I-XII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species (a ***specific immunoglobulin or fragment thereof and species of detectable label***, for example, a modified 4-chain immunoglobulin comprising a variable VH region that is modified to be partially replaced by a VH devoid of a CH1 domain and wherein the immunoglobulin specifically binds an HBV surface antigen and a radioisotope) to which claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

8. **If Applicant elects the Invention of one of Groups II-IX**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method and a specific detectable label ***if*** one is present (a ***specific immunoglobulin or fragment thereof and species of detectable label***, for example, a modified 4-chain immunoglobulin comprising a variable VH region that is modified to be partially replaced by a VH devoid of a CH1 domain and wherein the immunoglobulin specifically binds an HBV surface antigen and a radioisotope) to which claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. **If Applicant elects one of the GROUPS encompassed by X**, Applicant is further required to (1) elect a single disclosed species of VH containing immunoglobulin or fragment thereof to be used in the claimed method (a ***specific immunoglobulin or fragment thereof***, for example, a modified 4-chain immunoglobulin comprising a variable VH region that is modified to be partially replaced by a VH devoid of a CH1 domain) to which claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

10. **If Applicant elects the Invention of Group XI**, Applicant is further required to (1) elect a single disclosed species of VH containing immunoglobulin or fragment thereof that is specific for a specific protein to be used in the claimed method (a ***specific immunoglobulin or fragment thereof***, for example, a modified 4-chain immunoglobulin comprising a variable VH region that is modified to be partially replaced by a VH devoid of a CH1 domain and wherein the immunoglobulin specifically binds to a cyclin) to which claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

11. **If Applicant elects the Invention of Group XII**, Applicant is further required to (1) elect a single disclosed species of VH containing immunoglobulin or fragment thereof that is specific for a specific protein to be used in the claimed method (a ***specific immunoglobulin or fragment thereof***, for example, a modified 4-chain immunoglobulin comprising a variable VH region that is modified to be partially replaced by a VH devoid of a CH1 domain and wherein the immunoglobulin specifically binds to CD28) to which claims would be restricted if no generic claim is finally held to be allowable, and (2) to list all claims readable thereon including those subsequently added.

12. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

15. Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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